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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/672,074	09/29/2003	Paula Sundstrom	48544-00012	7985
26259	7590	03/08/2006	EXAMINER	
LICATLA & TYRRELL P.C. 66 E. MAIN STREET MARLTON, NJ 08053			SAIDHA, TEKCHAND	
			ART UNIT	PAPER NUMBER

1652

DATE MAILED: 03/08/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/672,074	Applicant(s) SUNDSTROM, PAULA	
	Examiner Tekchand Saidha	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) 33-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>1.16.04 & 6.9.05</u> . | 6) <input type="checkbox"/> Other: _____ |

Detailed Action

1. This CIP of 09/801,774, now USP 6,706,688, file 9/29/2003 is acknowledged. Claims 1-45 are present in this application.

2. Claims 1-45 are subject to the following restriction requirement under 35 U.S.C. 121:

- I. Claims 1-32, drawn to a method of altering expression of the *Candida albicans PDE2* gene (phosphodiesterase-2 gene), classified in class 435, subclass 6 by inhibiting *PDE2* gene expression.
- II. Claims 33 & 35-45 (in-part), drawn to a method of altering expression of the *Candida albicans CAP1* gene (Adenylate Cyclase-Associated Protein gene), classified in class 435, subclass 6.
- III. Claims 33 & 35-45 (in-part), drawn to a method of altering expression of the *Candida albicans PDE2* gene (phosphodiesterase-2 gene) by altering cAMP levels, classified in class 435, subclass 6.
- IV. Claim 34, drawn to a microarray comprising at least one nucleotide sequence or fragment thereof, of *C. albicans PDE2* gene, or *C. albicans CAP1* gene, classified in class 435, subclass 287.2.

3. The inventions are distinct, each from the other because of the following reasons:

The methods of Inventions I, II and III require different products and steps and have different endpoints. Therefore, Inventions I, II and III are patentably distinct.

The microarray of Invention IV comprises at least one nucleotide sequence of *C. albicans PDE2* gene, or *C. albicans CAP1* gene. However, the microarray is not required for the methods of Inventions I, II or III, are therefore patentably distinct from each other.

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4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. During a telephone conversation with Ms. Jane Massey Licata a provisional election was made with traverse to prosecute Invention I, Claims 1-32. Affirmation of this election must be made by applicant in replying to this Office action. Claims 33-45 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Claims 1-32 are under consideration in this application.

8. ***Continuation of prior application***

This application claims the benefit (CIP) of US Non-Provisional Application No. 09/801,774, filed 9 March, 2001 has been entered following the title of the invention or as the first sentence of the specification. But the present status of the application (now US Patent 6,706,688) should be included. Correction is required.

9. ***Drawings***

The drawings were received on 1/16/2004. These drawings, i.e. Figures 3 & 13 are not legible. Replacement sheets to the figures are required.

10. ***Sequence Rules***

The instant specification on pages 70-72, present primer sequences; and Figure 3 present amino acid sequences that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2), but fails to comply with the requirements. According to 37 CFR 1.821-825, every disclosed amino acid sequence of four or more residues or 10 or more nucleotides must be identified by a SEQ ID NO. The amino acid sequences presented do not have SEQ ID NOs. In order to comply with the sequence rules Applicants must identify these sequences by providing SEQ ID NO:, and where required provide a new version of the sequence listing and disk.

If the sequences are already present in the sequence listing provided to the PTO – Applicants may amend the specification appropriately by adding the required SEQ ID NO: following the sequence. In case of Figure 3, the legend may be amended as has been done for Figure 13.

However, if new sequences are added, Applicant must submit a new CRF copy and a new paper copy of the Sequence Listing, a statement that the content of the paper and computer readable copies are the same and where applicable include no new matter as required by 37 C.F.R. j 1.821(e) or 1.821(9) or 1.821(g) or 1.825(d), as well as an amendment directing its entry into the specification.

Applicant's cooperation is requested in discovering unidentified (without SEQ ID NO:?) sequences of which applicant may become aware in the specification.

New Sequence Rules

Since the effective filing date after July 1, 1998, Applicants should follow the New Rule Format and submit a new Sequence Listing (both in electronic and paper format). Compliance according to the requirements of 37 CFR 1.821 through 1.825 is required.

Specification

11. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

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12. *Written Description*

Claims 1-32 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. These claims are directed to a method for altering the *Candida albicans PDE2* gene which effects the virulence properties of *C. albicans* by inhibiting expression of said *PDE2* gene comprising, wherein the expression is inhibited by a variety of ways including - interfering with *PDE2* gene transcription mediated by *cis*-regulatory sequences, a DNA binding protein (BP), etc., the claimed genus with no defined structure of the altered *PDE2* gene.

The specification does not contain any disclosure or description of the altered *PDE2* gene sequence (SEQ ID NO:?). The genus of *PDE2* genes that comprise these above altered *PDE2* gene molecules is a large variable genus with the potentiality of encoding many different proteins. Therefore, many functionally unrelated altered *PDE2* gene sequences are encompassed within the scope of these claims. The specification discloses single altered or disrupted *PDE2* gene sequence of SEQ ID No. 13 encoding PDE of the claimed genus which is insufficient to put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

13. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps in claim 1 (for example) to include ways of altering expression, which from the instant

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specification (see for example, page 83) appears to be disruption of *PDE2* gene from *C. albicans* by replacing 1388-bp of the coding region (UTR) of *PDE2* with the 4.0-kbp *Bam*Hi- *Bg*/II ... as per Example 18 of the instant specification.

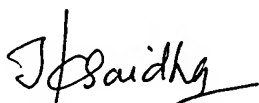
Dependent claims 2-32 are included in the rejection for failing to correct the defect present in the base claim(s).

14. No claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tekchand Saidha whose telephone number is (571) 272 0940. The examiner can normally be reached on 8.30 am - 5.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272 0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Tekchand Saidha

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March 1, 2006